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10/029,871	12/31/2001	Yukio Iino	217543US0CONT	4043

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/21/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,871

Applicant(s)

Yukio Iino et al

Examiner

SUDHAKER PATEL, D.Sc. Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 24, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No. 9
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No. 6,8 6) ☐ Other:

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DETAILED ACTION

Applicants' communication paper # 7/24/02 is acknowledged.

Claims 1-17 relate to compounds of Formula (I). Claim 18 is related to composition of the compounds of Formula (I), and claims 19-20 are related to pharmaceutical activity. Therefore, the claims in this application are the claims 1-20.

I. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d), but not considered, and therefore not granted for following reasons:

(1). The reference WO 01/94353 which is used in the 35 U.S.C. 102(a) rejection as an intervening reference with following data of record. **(A)**. U.S. Application Sr. NO. 10029871 filing date: 12/31/2001. **(B)**. CON of PCT/JP00/04298 is dated 6/29/2000. **(C)**. Foreign priority is claimed to (I). JAPAN 2000-71706 dated 3/15/2000, and (II). JAPAN 11-187959 dated 7/1/1999.

Therefore, the applied reference '353 falls in between the CON PCT date and the filing date of the application.

(2). The priority as claimed is not considered valid because an English Translation of the PCT application is not on record. See MPEP 1895.01.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of CON of PCT/JP00/04298 filed 6/29/2000 has not been made of record in accordance with 37 CFR 1.55. See MPEP § 1895.01.

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Election/Restriction

II. Examiner had requested applicants on 5/3/02 for oral restriction/election, and applicants had elected species of Example 43 wherein A = Pyridyl in Formula (I) of claim 1.

Upon further consideration and in view of many embodiments encompassed by the generic Formula : " R1=CO-N(R2)-A-X-B-N(R3)-Y-(CH2)*n*-R4", many different issues of patentability that exist for compounds of Formula(I) as evidenced by the arts applied(Luzzio et al (WO 2001094353) pertinent to Group I below, prior art Arcamone et al (WO 9313739) pertinent to Group II below, and art not applied (EP 102476), restriction is necessary in the following way:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims (in part) 1-20, drawn to compounds, composition, and a method of use for the Formula (I) wherein in R1 = cycloalkyl/cycloalkenyl; A =pyridine; B = Aromatic ring or heterocyclic ring, classified in class 546, subclasses various depending on the nature of variables. If this group is elected, a single species with all variables must be exactly disclosed.

Group II. Claims(in part) 1-20, drawn to compounds not included in above Group I e.g. A = pyrimidine, pyrazine, classified in class 544, subclasses various depending on the nature of variables. If this Group is elected further restriction will be required as there are many variables.

The inventions are distinct, each from the other because:

Compounds of Groups I-II are drawn to structurally diverse compounds that are made and used independently of each other, are separately classified, require separate literature searches and

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are not art recognized equivalents. Note the art cited by examiner WO '353 is relevant to Group I, art Arcamone et al (WO 9313739) is pertinent to non-elected Group II, and EP '476 is not used although it teaches making of compounds with bridge similar to instant X variable, it is not teaching making of heterocyclic compounds as claimed herein.

Applicants' elected species falls within Group I which has been searched by the examiner.

Applicants are advised that the claims will only be examined with respect to Group I subject matter as inclusion of Group II will involve additional search which is time consuming and burdensome to examiner.

First action on merits follows.

III.

Information Disclosure Statement

Applicants' Information Disclosure statements submitted as Paper # 3/25/02 and paper # 8 submitted on 7/24//02 are considered by the Examiner and signed copies of the same are enclosed with this communication for applicants' record.

IV.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 1,2,18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Luzzio et al (WO 2001094353). Compounds having CAS RN # 380-34-0 (= Cyclobutanecarboxamide, N-[1-[[7-[(2-methyl-1H-indol-5-yl)amino]thieno[3,2b]pyridine-2-yl]-3-pyrrolidinyl) and CAS RN # 380236-58-8 (= Cyclobutanecarboxamide, N- methyl-N-[1-[[7-[(2-methyl-1H-indol-5-yl)amino]thieno[3,2b]pyridine-2-yl]-3-pyrrolidinyl) read on instant claim 1 in the following way for the Formula (I) variables:

R1 = Cycloalkyl(= cyclobutyl);

CO = CO;

NR2=NH/Nalkyl =N-CH3- or NH;

A=heterocyclic ring =pyrrolidine(see instant specification page 9 line 2);

X =CO;

B =Heterocyclic ring;

NR3=NH =NH;

Y =Bond;

R4 =aromatic heterocyclic group.

Note, the reference also teaches the utility of the compounds as “anticancer agents”.

Applicants can not rely on the filing date of PCT/JP00/04298 application to over come the above rejection because a copy of the application and the English Translation of said application has not been made of record. See MPEP§ 1895.01.

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V.*Claim Rejections - 35 U.S.C. § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Arcamone et al (WO 9313739). Compound having CAS RN # 150691-34-2(1H-Pyrrole-2,4-dicarboxamide, N2-(3-amino-3-iminopropyl)-N4-[4-[[[4-[(cyclopropylcarbonyl)amino]1-methyl-1H-pyrrole-2-yl]carbonyl]amino]-1-methyl-1H-pyrrol-2-yl]-1-methyl-, monohydrochloride, read on the compounds claimed herein which fall in non-elected invention of Group II. The reference '739 compound read on instant claim 1 in the following way for the Formula (I) variables:

R1	= Cycloalkyl(= cyclopropyl);
CO	= CO;
NR2=NH/Nalkyl	= NH;
A=heterocyclic ring	=pyrrole;
X	=CONH;
B	=Heterocyclic ring;
NR3=NH	=CO;
Y	=Bond;
R4	=aromatic heterocyclic group.

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Note, the reference also teaches the utility of the compounds as “anticancer agent analogues”.

VI.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

A). Claims 1-17 recite: “Compound and pharmaceutically acceptable salt thereof”. It is not very clear if a compound or the salt is claimed or a mixture of compound and salt is claimed. It is suggested to replace by: “A compound or pharmaceutically acceptable salt thereof”.

B). Claim 18 is recited as: “a pharmaceutical composition comprising as an active ingredient a heterocyclic compound...”;

Claim 19 is recited as: “An AP-1 activation inhibitor or a NF-kappaB activation inhibitor comprising as an active ingrediaent a heterocyclic compound...” , and

Claim 20 is recited as: “An inflammatory cytokine production inhibitor, a production for matrix metalloprotease or an inflammatory cell adhesion factor expression inhibitor comprising as an active ingredient a heterocycli compound...”.

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Claims 18-20 as recited are related to compositions of compounds of claim 1, and therefore, it is not very clear as to what applicants want to claim exactly in these 3 claims.

Also, correction of : "a heterocyclic compounds according to claim 1..." to " an active ingredient which is a heterocyclic compound..." is required.

VII.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

S.p.

May 14, 2003.



Mukund J. Shah
MUKUND SHAH

SUPERVISORY PATENT EXAMINER

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